REMARKS/ARGUMENTS

Claims 50-53, 56, 57, 60-63, 68-73, 78-83, 88 and 89 stand rejected under 35 U.S.C. §102(b) as being anticipated by Chaser® or based upon a public use or sale of the invention. In addition, claims 58, 59, 64, 65, 74, 75, 84 and 85 stand rejected under 35 U.S.C. §103(a) as unpatentable over Chaser®, and claims 54, 55, 66, 67, 76, 77, 86 and 87 stand rejected under 35 U.S.C. §103(a) over Chaser® in view of the article entitled "Hangover-Helping Product" from goaskalice.columiba.edu. Applicants traverse these rejections for at least the following reasons.

The Examiner inquired about the sufficiency of the record surrounding the use raised by the Examiner regarding the Chaser® publication. Specifically, the Examiner comments that the "the record must address the time, place and circumstance of the use" and that the "declaration states that the attached 'Confidentiality Agreement' governed the parties conducting the studies but does not provide evidence that said agreement was signed by all parties."

A use is a public use under §102(b) if the inventor did not retain sufficient control over the invention during the use. Such control is evaluated by reviewing the time, place and circumstances of the use.[1] "The presence or absence of a confidentiality agreement is not itself determinative of the public use issue, but is one factor to be considered."[2]

As the attached Declarations of Mr. Crippen and Mr. Morse indicate, the time, place and circumstances surrounding the use in question illustrate that the inventors of the present application never relinquished control over their invention so as to create a barring public use under §102(b). Specifically, Mr. Crippen declares that, during his early use of this substance, only himself, his wife, and two children consumed these compositions, and that neither his wife or children knew what these compositions were made of. Furthermore, these experiments took place in the privacy of his home, and no one else was aware of these experiments. Accordingly, Mr. Crippen did not relinquish control over his invention by conducting this study, so as to make this use public.

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[1] MPEP 2133.03(a), citing *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1265 (Fed. Cir. 1986).
[2] *Id.*

Similarly, Mr. Morse declares that three studies were conducted after this technology was licensed from Mr. Crippen.[3] None of these studies constitute a public use. The first study, for example, was conducted by a co-inventor and is reported in the instant application. The test subjects of this study were never informed about the identity of the composition they received, and at no point during this experiment were the test formulations released from the control of the inventor. Accordingly, this use is not public because the inventor never relinquished control of this formulation, but rather only conducted a limited study to test the invention.

The second study mentioned by Mr. Morse was conducted by a group of clinical investigators in Michigan on or about February 2001. Here, as in the first study described by Mr. Morse, no subject was informed about the identity of the test substance. Still further, the clinical investigators performing the study were specifically prohibited from disclosing the nature of the formulations being tested by the Confidentiality Agreement (as earlier submitted in the Declaration of January 16, 2004).[4]

Applicants note that the Examiner finds that "there is no mention that subjects of the study were subject to a confidentiality agreement." However, Applicants submit that the attached declarations illustrate that the subjects themselves, although never under a formal confidentiality agreement, were also *never aware of the composition of the test substance.* Thus no public disclosure of the formulation itself was made during the course of this study, because none of the inventors relinquished control of the inventive formulation.

The third study described by Mr. Morse occurred on or about November 2002, which is after the critical date of the present invention, and thus not a barring event under 35 U.S.C. §102(b).

Finally, the Examiner states that "[t]here is no factual evidence of record to compare the scope of the claimed invention to that of the use disclosed in the reference." The Applicants, although somewhat uncertain as to exactly what comparison the Examiner is requesting, submit that the record is now adequately developed for the Office to determine that the use mentioned in the reference was not *public*.

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[3] Applicants submit that the present declarations now adequately address the Examiner's concerns regarding "the extent and timing of the clinical studies performed and their relations to the critical date."

[4] The Applicants submit that this also addresses the Examiner's concern that "there is no factual evidence of record that the Exhibits apply to the invention as claimed."

Accordingly, as the attached Declarations set forth, along with the evidence of record, the uses referred to in the Chaser publication relate only to above described evaluation and pre-market activities of this product and were not public uses under 35 U.S.C. 102(b). Therefore, the Applicants respectfully request the reconsideration and withdrawal of these rejections in light of the above remarks and attached declarations.

CONCLUSION

Since the prior art of record does not disclose or suggest the invention as disclosed and claimed herein, the present application is believed to be in condition for allowance, and such action is hereby solicited.

Should any issues remain unresolved, the Examiner is encouraged to contact the undersigned attorney for Applicants at the telephone number indicated below in order to expeditiously resolve any remaining issues.

Respectfully submitted,

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Attachments: Declarations of Raymond Crippen
and Thomas Morse